

REMARKS

Claims 1-14, 16, 18-20, 22-24, 26, and 28-39 were rejected by the Examiner. Claims 4-8, 12-14, 16, 18-20, 27, and 29-30 have been cancelled. Claims 1, 9, 23, 28 and 33 have been amended. New claims 40-80 have been added. In light of the amendments and remarks herein, reconsideration of Claims 1-3, 9-11, 15, 17, 21-25, 27-28, and 31-80 is respectfully requested.

Amendments to the Specification

The Specification has been amended to address the Examiner's objections. No new matter has been added to the Specification.

Amendments to the Claims

While Applicants believe that the previously presented claims are patentable over all of the art cited in the Office Action as well as all other references submitted by Applicants, the claims have nonetheless been amended as follows. The amendments are therefore made without prejudice or disclaimer, and Applicants reserve the right to pursue the original scope of the claims as provided prior to the cancellation or amendments, such as through continuation practice.

Claim 1 is amended to recite an apparatus configured to irradiate phototherapeutic radiation from within the oral cavity and in the direction of a region of tissue other than oral tissue. Support for this amendment is found throughout the specification, including specification paragraphs 69, 80, 130-131, and 140. Those paragraphs disclose various aspects of the invention, including the irradiation of facial tissue from within the oral cavity to treat various skin conditions such as acne.

Claim 9 is amended to recite an apparatus that irradiates a region of a mucosal lining of the oral cavity with the phototherapeutic radiation, and configured to emit phototherapeutic radiation having a power density sufficient to penetrate the mucosal lining. Support for this amendment is found throughout the specification, including specification paragraph 130.

Claims 23 and 33 are amended to correct grammatical errors.

Claim 28 is amended to recite an apparatus configured to conduct heat from the apparatus to the tissue, wherein the device is further configured to induce hyperthermia in the tissue. Support for this amendment can be found in several locations in the specification, including in specification paragraphs 074, 121-127, 141-143, and 150.

New claims 40-80 have been added. Support for these claims can be found throughout the specification, and particularly in the section of the specification entitled "Soft Tissue Treatments," at paragraphs 129-151.

As such, the amendments to claims 1, 9, 23 and 28 do not add any new matter.

Double Patenting

The Applicants gratefully acknowledge the Examiner's decision to tentatively withdraw the provisional obviousness-type double patenting rejections.

Claim Rejections - 35 U.S.C. § 102

Claims 1-3, 9, 28, 31-35 and 38-39

Claims 1-3, 9, 28, 31-35 and 38-39 stand rejected under 35 U.S.C. §102(b) as being anticipated by WO 98/06456 to Chen et al. (herein "Chen"). These claims are novel, however, because Chen fails to disclose all of the elements recited in the claims. For example, Claim 1 recites and apparatus having an emitter "configured to irradiate phototherapeutic radiation from within the oral cavity and in the direction of a region of tissue other than oral tissue" and "configured to emit phototherapeutic radiation having at least one wavelength at a power density sufficient to irradiate the region of tissue from within the oral cavity."

Applicants disclose various devices that specifically treat facial tissue by irradiating the tissue from within the oral cavity. For example, Applicants disclose:

In another aspect, the biostimulating radiation is primarily directed to soft tissue in the oral cavity, e.g., facial tissue. In some embodiments, the oral cavity is

irradiated so as to deposit a dose of radiation below the facial skin dermatological or cosmetic condition, such as acne.

(Application ¶ 16; see also ¶¶ 69, 80 and 130.)

In comparison, Chen does not disclose irradiating the facial tissue from within the oral cavity. Instead, Chen discloses a mouthpiece that fits over a patient's teeth to irradiate the gum line. (See, e.g., Chen 3:12.) Chen discloses that "light is delivered to a treatment site extending along the gum line in a patient's mouth." (Chen 5:3-4.) The embodiments of Chen are devices that "treat disease in an oral cavity" and do so by treating the gum line in the oral cavity. (See, e.g., Chen 3:34, 5:13, 6:8-12 and 28-34, 7:11-22, and 8:7-16 and 18-20.)

Regarding claim 9, assuming *arguendo* that Chen is *capable* of radiating areas other than the teeth and gums, as the Examiner suggests at page 4, there still is no disclosure indicating that the device of Chen is capable of radiating tissue other than oral tissue. In other words, there is no disclosure that Chen is "configured to emit phototherapeutic radiation having a power density sufficient to penetrate the mucosal lining" or "configured to emit phototherapeutic radiation having at least one wavelength at a power density sufficient to irradiate the region of tissue from within the oral cavity" as claimed.

Claims 2-3, 9, 28, 31-35 and 38-39 are novel for at least the same reasons that Claim 1 is novel. Accordingly, claims 1-3, 9, 28, 31-35 and 38-39 are novel and patentable over Chen.

Claims 1, 9-11, 23 and 37

Claims 1, 9-11, 23 and 37 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,862,771 to Muller (herein "Muller"). These claims are novel, however, because Muller fails to teach or suggest the elements recited in the amended claims.

Muller discloses irradiating teeth using radiation to cause deposits on the surface of a tooth to fluoresce in order to detect the presence of deposits that need to be removed, for example, by brushing with the head of a toothbrush. In short, Muller discloses using the device to detect biological deposits on the tooth. For example, Muller states:

In use the toothbrush of the invention is used to brush the user's teeth, thereby aligning the bristle face 3 so that it faces the tooth surface at a convenient distance. The control 176 is operated, and incident radiation is directed in the direction 5 from the source 173, being reflected by dichroic mirrors 179, 180 onto a tooth surface using the toothbrush head 1 of this invention, for example via the filaments 113. Fluorescence radiation is emitted from the tooth surface, either from biological deposits such as plaque or from a deposit-free tooth surface or from both. This emitted radiation is collected by the head 1, e.g. again via filaments 113 and directed back as described above to the detector 174, being transmitted through the dichroic mirror 180. An electrical signal is generated by the detector 174 and is processed by the processing device 177. The processing device 177 operates the signaling means 178 to indicate to the user the presence or absence of biological deposit.

(Muller Col. 14:59 to 15:8.) Muller does not disclose the treatment of tissues other than oral tissue as recited in claim 1.

As discussed above with regard to Chen, assuming *arguendo* that Muller is *capable* of radiating any area within an oral cavity, as the Examiner suggests at page 5, there is no disclosure indicating that the device of Muller is “configured to emit phototherapeutic radiation having at least one wavelength at a power density sufficient to irradiate the region of tissue from within the oral cavity” as claimed.

Claims 9-11, 23 and 37 are novel for at least the same reasons that Claim 1 is novel. Accordingly, claims 1, 9-11, 23 and 37 are novel and patentable over Muller.

Claims 1 and 10-11

Claims 1 and 10-11 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 6,239,442 to Iimura (herein “Iimura”). These claims are novel, however, because Iimura fails to disclose all of the elements recited in the claims. For example, as discussed above, Claim 1 recites and apparatus having an emitter “configured to irradiate phototherapeutic radiation from within the oral cavity and in the direction of a region of tissue other than oral tissue” and “configured to emit phototherapeutic radiation having at least one wavelength at a power density sufficient to irradiate the region of tissue from within the oral cavity.”

As similarly discussed above with regard to Chen and Muller, Iimura does not disclose these elements. Iimura discloses cleaning heads that employ ultraviolet radiation. The cleaning heads are broadly applicable to various purposes including vacuum cleaners and mops. (See Iimura col. 1, lines 10-16.) Iimura's cleaning heads, whether used for oral or other cleaning purposes, simply do not include all the elements of claim 1.

Claims 10-11 are novel for at least the same reasons that Claim 1 is novel. Accordingly, claims 1 and 10-11 are novel and patentable over Iimura.

Claims 1, 5 and 6

Claims 1, 5 and 6 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Publication 2001/0024777 to Azar et al. (herein "Azar"). (Note: claims 5 and 6 have been cancelled.) Claim 1 is novel, however, because Azar fails to disclose all of the elements recited in the claims. For example, as discussed above, Claim 1 recites an apparatus having an emitter "configured to irradiate phototherapeutic radiation from within the oral cavity and in the direction of a region of tissue other than oral tissue" and "configured to emit phototherapeutic radiation having at least one wavelength at a power density sufficient to irradiate the region of tissue from within the oral cavity."

As similarly discussed above, Azar does not disclose these elements. Azar generally discloses the destruction of bacteria within the oral cavity by applying radiation that has a wavelength of absorption other than that of oxyhemoglobin. (See, e.g., Azar paragraph 81.) The device of Azar does not include, and Azar does not disclose, all the elements of claim 1.

Accordingly, claim 1 is novel and patentable over Azar.

Claims 1, 22 and 24

Claims 1, 22 and 24 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent 6,572,637 to Yamazaki et al. (herein "Yamazaki"). These claims are novel, however, because Iimura fails to disclose all of the elements recited in the claims. For example, as discussed above, Claim 1 recites an apparatus having an emitter "configured to irradiate

phototherapeutic radiation from within the oral cavity and in the direction of a region of tissue other than oral tissue” and “configured to emit phototherapeutic radiation having at least one wavelength at a power density sufficient to irradiate the region of tissue from within the oral cavity.”

As similarly discussed above, Yamazaki does not disclose all of the claimed elements. Yamazaki discloses a “handbreadth-sized laser beam projecting probe for beauty treatment.” (See Yamakazi Abstract.) Regardless of whether that device may be suitable for dental purposes, there is no disclosure regarding the oral cavity generally or the elements of claim 1 specifically.

Claims 22 and 24 are novel for at least the same reasons that Claim 1 is novel. Accordingly, claims 1, 22 and 24 are novel and patentable over Yamakazi.

Claims 1 and 36-37

Claims 1 and 36-37 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent 6,443,978 to Zharov (herein “Zharov”). These claims are novel, however, because Zharov fails to disclose all of the elements recited in the claims. For example, as discussed above, Claim 1 recites an apparatus having an emitter “configured to irradiate phototherapeutic radiation from within the oral cavity and in the direction of a region of tissue other than oral tissue” and “configured to emit phototherapeutic radiation having at least one wavelength at a power density sufficient to irradiate the region of tissue from within the oral cavity.”

Zharov does not teach such a device. Zharov instead discloses a “physiotherapeutic irradiation of spatially extensive pathologies” using “sources of optical radiation ... placed on the surface of a substrate....” (See Zharov Abstract.) Zharov does not disclose a device that is configured to treat non-oral tissue from within the oral cavity, and does not discuss such a treatment even in passing or as a potential alternate embodiment.

Claims 36 and 37 are novel for at least the same reasons that Claim 1 is novel. Accordingly Claims 1 and 36-37 are patentable over Zharov.

Claim Rejections - 35 U.S.C. § 103

Although Claim 20 was rejected under 35 U.S.C. § 103(a), claim 20 has been cancelled.


CONCLUSION

In summary, the above-identified patent application has been amended and reconsideration is respectfully requested for all the reasons set forth above. In the event that the Examiner deems that the amendments and remarks do not overcome the stated grounds for rejection, the Applicants kindly request that the Examiner telephone the undersigned representative to discuss any remaining issues.

Respectfully submitted,

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